DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0433]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by February 4, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Threshold of Regulations for Substances Used in Food-Contact Articles—21 CFR 170.39—(OMB Control Number 0910–0298)—Extension

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless it either conforms to the terms of a regulation prescribing its use or to an exemption for investigational use. Consequently, the safety of the substance under its intended conditions of use must be established, and a food additive regulation issued, before the substance can be used in food. In accordance with section 409 of the act, manufacturers of all components of a food-contact article (e.g., food packaging or food processing equipment) whose use meets the food additive definition in sections 201(s) of the act (21 U.S.C. 321) must submit a petition establishing the safe conditions of use before such food-contact articles may be marketed, unless they are the subject of an exemption for investigational use under section 409(i) of the act.

Section 170.39 (21 CFR 170.39) establishes a process that provides a manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation (60 FR 36582, July 17, 1995). The agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration is at or below 0.5 parts per billion. The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

In order to determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes: (1) The chemical composition of the substance for which the request is made, (2) detailed information on the conditions of use of the substance, (3) a clear statement of the basis for the request for exemption from regulation as a food additive, (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance, (5) results of a literature search for toxicological data on the substance and its impurities, and (6) information on the environmental impact that would result from the proposed use.

FDA uses this information to determine whether the food-contact article meets the threshold criteria. Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (i.e., food packaging and food processing equipment) or of the articles themselves.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.39	60	1	60	88	5,280

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The previous annual reporting estimate is based on information received from representatives of the food packaging and processing industries and on agency records. FDA typically receives 60 threshold of regulation exemption requests per year. These requests require between 28 to 108 hours (h) to prepare.

The agency received two comments to the **Federal Register** of December 10, 1996 (61 FR 65067), from two trade associations; one that represents the plastic food-packaging industry and one that represents companies that market packaged food. The issues raised by these comments, and the agency's response to them, are set forth as follows.

1. One comment fully supported and endorsed the threshold of regulation process established by § 170.39 but expressed the opinion that the current requirement that an environmental assessment (EA) accompany each exemption request is an undue paperwork burden. The comment expressed the view that the considerable effort involved in preparing an EA for

every exemption request is grossly out of proportion to the minimal increment in protection of the environment that may be gained. The comment proposed an alternative approach whereby an EA would be required only in extraordinary circumstances (i.e., where significant adverse environmental impacts may occur that are not subject to regulation by other authorities).

The comment did note that FDA had published a proposed rule (National Environmental Policy Act (NEPA): Proposed Revision of Policies and Procedures; in the **Federal Register** of April 3, 1996 (61 FR 14922); republished May 1, 1996 (61 FR 19476), that would eliminate the requirement for EA's for certain types of actions resulting from requests for exemption from regulation as a food additive under § 170.39 and that would also eliminate the requirement for information on possible environmental effects at the sites of manufacture of all FDA-regulated substances. This comment, submitted by a trade association, noted that the association also submitted a comment to the agency on the proposed NEPA rule. The association's comment on the proposed NEPA rule is essentially identical to the present comment outlined in the preceding paragraph.

In the **Federal Register** of July 29, 1997 (62 FR 40570), the agency published a final rule revising its NEPA policies and procedures (''the final NEPA rule''). The final NEPA rule was issued after the agency reviewed and addressed the comments received on its April 3, 1996, proposed rule, including the comment submitted by the trade association, summarized previously.

As discussed in detail in the preamble to the final NEPA rule (62 FR 40579 through 40581), the agency agreed in part with the comment and expanded the scope of actions included in two categorical exclusions § 25.32(i) and (j) (21 CFR 25.32(i) and (j)), including actions on requests for exemption from regulation under § 170.39. However, as further discussed in the preamble to the final NEPA rule, the agency did not agree completely with this comment. Specifically, FDA concluded that certain classes of actions on food-contact materials should continue to require EA's and that the preparation of EA's for requests for these actions is not unduly burdensome for the industry. The § 170.39 exemption requests that continue to require an EA are, for the most part, for actions on substances present at greater than 5 percent of finished food-packaging materials that are not components of coatings and for actions on substances present at 5 percent or less of finished food-packaging materials that are not expected to remain with finished food-packaging materials through use by consumers. As the agency explained in the preamble to the final NEPA rule, actions on these types of substances have the potential for significant environmental impact, and such potential can be evaluated only by the agency's review of EA's prepared by requesters. In accordance with 21 CFR 25.21, EA's are also required for those actions where extraordinary circumstances indicate that there may be significant environmental effects, even though the actions belong to a class that ordinarily would warrant exclusion from the requirement to prepare an EA. Guidance on preparing EA's is available from the Food and Drug Administration's Office of Premarket Approval (HFS–200), 200 C St. SW., Washington, DC 20204.

In addition to the review summarized previously that resulted in the agency expanding the scope of two categorical exclusions (§ 25.32(i) and (j)), the agency has also reviewed the types of uses of food-contact articles that have been the subject of exemption requests received since the threshold of regulation process was implemented on August 16, 1995. The agency estimates that the percentage of uses that will qualify for categorical exclusion under the agency's revised NEPA regulations may be as high as 8 percent. It is further estimated that those exemption requests that qualify for categorical exclusions will require, on average, 48 h to prepare as opposed to the 88 h typically required to prepare exemption requests that include an EA. This would represent a 45 percent reduction in paperwork burden for such requests. The overall paperwork burden associated with the threshold of regulation process would also decrease dramatically. Prior to implementation of the amended NEPA regulations, the annual industry burden associated with threshold of regulation exemption requests was estimated to be 5,280 h based on the assumption that the agency receives 60 requests per year and that each request requires on average 88 h to prepare. If, as projected, 87 percent of threshold of regulation exemption requests qualify for the categorical exclusions discussed previously, it is estimated that the overall paperwork burden would decrease to 3,200 h (52 requests x 48 h + 8 requests x 88 h). This would represent a 39 percent overall reduction in paperwork burden.

2. One comment asserted that the requirement that a manufacturer of a substance submit an exemption from regulation request to FDA is not necessary for the proper performance of FDA's functions. Instead, the comment argued that manufacturers should be able to make their own determination as to whether the use of a substance in a food contact article meets the criteria for exemption set out in § 170.39. The comment further asserted that allowing self-determinations of exemption status would substantially reduce the burden on industry.

FDA disagrees with this comment for several reasons. In the preamble to the final rule issuing § 170.39, the agency responded in detail to comments recommending that manufacturers be permitted to determine themselves whether use of a substance is entitled to an exemption from the food additive listing regulation requirement (60 FR 36582 at 36586 through 36587. In that response, the agency explained that under *Monsanto* v. *Kennedy*, 613 F. 2d 947 (D.C. Cir. 1979), only the Commissioner of Food and Drugs has the authority to exempt a substance from regulation as a food additive. The agency's response also discussed in detail the policy rationale underlying the procedure in § 170.39 (i.e., that a process wherein the agency determines which substances will be exempt from regulation as food additives will be binding on the agency and will ensure more consistent exemption decisions). For the same reasons discussed in the preamble to the final rule, FDA concludes that this comment does not provide a basis for altering the information collection requirements of § 170.39.

Dated: December 24, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0374]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Latex Condoms; User Labeling; Expiration Dating'' has been approved